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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,156	10/25/2001	Samuel L. Forusz	70452P001C	3099

8791 7590 12/31/2002

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,156

Applicant(s)

FORUSZ ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 for the reasons set forth in the prior Office Action and the further reasons below:

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In the parent Application, the limitation "an organic acid in an amount up the equivalent amount of calcium" was not specifically set forth in the Specification. The limitation was based on a calculation of the amounts of citric and malic acid relative to the calcium in an example set forth in the Specification. Examiner allowed the parent application with the proviso that a supplemental declaration be submitted and that the acid be limited to organic acid as citric and malic acid are organic acids. The mere fact that acids and/or acidifiers in general were disclosed by the parent Applicant does not overcome the priority issue herein for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-8, 10,11,14-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acids such as ascorbic acid, malic acid and citric acid and solubilizers such as maltol, maltodextrin and carrageenan and xanthan gum does not

reasonably provide enablement for all acidifiers or solubilizers for the reasons set forth in the prior Office Action and the further reasons below.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The fact that the Specification sets forth acids or acidifiers in general does not appear to overcome the rejection herein. The issue is whether the Specification enables acidifiers up to an equivalent of the calcium. As indicated above, Examiner allowed "organic acids" as the malic and citric acids are organic acids and were shown by calculation of the amounts set forth in an disclosed example to be present in an amount equivalent to the amount of calcium. This not the same as a disclosure that any acidifier can be used up to an equivalent of calcium. With respect to solubilizing the components, the Specification only appears to discuss solubilizing with respect to addition of maltol, maltodextrin and carrageenan and xanthan gum, and it is uncertain what other compounds would be suitable to solubilize the components. Finally, the fact that the Specification discloses solubilizers, acidifiers and/or stabilizers in general is not at issue. The issue is herein is that since relatively few examples of each are disclose it appears that a skilled artisan would be required to do undue experimentation in determine what other compounds or combinations thereof would be suitable as solubilizers, acidifiers and/or stabilizers.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1616

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-16,20,22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Liska et al. (US Pat. 6,051,260) for the reasons of record set forth in the prior Office Action and the further reasons below.

Liska et al. was disclosed in the prior Office Action and the same are incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the prior art does not disclose an acidifier, however, Applicant has not shown how the term "acidifier" excludes the acids set forth in the prior art composition nor has Applicant shown that there is not an amount of at least one acid which would fall within the range of above 0 to an equivalent of the amount of calcium present in the prior art composition. Examiner reminds Applicant that in a 102/103 inherency rejection the Graham v. John Deere factors are not applicable, as such, the argument relative to teaching or motivation to add an acidifier does not appear to overcome the rejection herein.

Claims 1-11,14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liska et al. (US Pat. 6,051,260) in view of Ohta et al. (US Pat. 5,900,255), Orafi, WO99/07392, Dulebohn et al. (US Pat. 6,171,633) and Patel et al. (US Pat. 6,150,399) for the reasons of record set forth in the prior Office Action in further view of Kochanowski (US 5,128,374) and the further reasons below.

Art Unit: 1616

Examiner notes the rejection herein does not apply to claimed subject matter which was found to be allowable in US App. No. 09/365,156.

Liska et al., Ohta et al., Orafti, WO 99/07392, Dulebohn et al., Patel et al. were discussed in the prior Office Action and the same are incorporated herein.

Kachanowski teaches that calcium compounds can be solubilized by mixing calcium salt and citric and malic acids, preferably at a molar ratio of 1:0.7 to about 1:0.9, which is effective in building bone (Column 3, lines 25-68, Column 4).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of calcium, inulin or fructooligosaccharide and a pH modifying organic acid or acidifier in an amount up to the equivalent amount of calcium. However, the prior art amply suggests the same as it is known that the components, such as inulin, vitamins, minerals, isoflavones are effective in treating osteoporosis and that calcium compounds may be solubilized by adding citric and malic acid in various amounts including up to an equivalent amount of calcium. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the composition would be effective in treating osteoporosis and that the components would be solubilized thereby avoiding the presence of precipitants.

Examiner has duly considered Applicant's arguments but deems them unpersuasive in light of the above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

Examiner notes that Applicant indicated that a terminal disclaimer was attached, however, no such terminal disclaimer accompanied Amendment (10/3/2002). As such, the double patenting rejection set forth in the prior Office Action is maintained and is not provisional as Application No. 09/365,156, is now Pat. No. 6,436,446.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

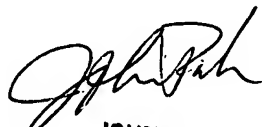
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

December 24, 2002


JOHN PAK
PRIMARY EXAMINER
GROUP 1200

